

REMARKS

Amendments

New claims 11-14 are directed to specific embodiments of claim 1 (e.g. p.4, lines 27-31). These amendments introduce no new matter.

35USC112, first paragraph (written description)

The Action queries whether the specification describes “in any fashion the physical and/or chemical properties of the claimed class of modified protein and characteristics and definition of the method [sic].” Action, p.3, lines 3-4.

The claims are directed to a method of detecting a post-translational modification of a predetermined protein expressed by a cell, comprising the step of: specifically detecting an O-sulfonation of a serine or threonine residue of the protein. The Specification describes the specific detection of O-sulfonation of a serine or threonine residue in diverse eukaryotes (e.g. p.11, line 9 – p.12, line 20). The Specification describes the use of a variety techniques for specifically detecting the O-sulfonation, including mass spectrometry, chemical analysis, radiolabeling, and specific antibodies (e.g. p.4, line 27 – p.6, line 8; p.11, line 17 – p.13, line 8). The Specification provides detailed protocols and working examples for these various detection methods including mass spectrometry (e.g. p.4, line 32 – p.5, line 9; p.10, line 27 – p.14, line 28); selective detection using single-chain sulfopeptide-specific phage antibodies (e.g. p.14, line 30 – p.17, line 11) and sulfopeptide-specific monoclonal antibodies (e.g. p.17, lines 13-29); and specific detection of chemically labeled O-serine and threonine sulfonation (e.g. p.8, line 15 – p.9, line 2; see also exemplification at p.19, lines 12-26). The specification amply describes and exemplifies the claimed methods.

35USC112, first paragraph (enablement)

The Action queries whether the specification provides enablement for detecting O-sulfonation of any protein using any method. The test for enablement is whether the specification enables one skilled in the art to practice the invention as claimed without undue experimentation.

The claims are directed to a method of detecting a post-translational modification of a predetermined protein expressed by a cell, comprising the step of: specifically detecting an O-

sulfonation of a serine or threonine residue of the protein. The Specification describes the specific detection of O-sulfonation of a serine or threonine residue in diverse proteins (e.g. p.11, line 9 – p.12, line 20); in particular, the specification demonstrates protein O-sulfonations in diverse proteins across diverse life forms including neuronal filament proteins of *Lymnaea stagnalis* (a freshwater snail), a cathepsin-C protein of *Plasmodium falciparum* (a malaria-causing parasite), and a tyrosine kinase (Ror2) of humans (p.9, lines 22-30; p.11, line 9 – p.12, line 20). Furthermore, the disclosed studies reveal a large number of proteins to be differentially sulfonated across differing physiological conditions, including injured versus non-injured axoplasms (p.13, line 13 – p.14, line 28).

The Specification describes the use of a variety of techniques for specifically detecting the O-sulfonation including using mass spectrometry, chemical analysis, radiolabeling, and specific antibodies (e.g. p.4, line 27 – p.6, line 8; p.11, line 17 – p.13, line 8). The Specification provides detailed protocols and working examples for these various detection methods including mass spectrometry (e.g. p.4, line 32 – p.5, line 9; exemplification at p.10, line 27 – p.14, line 28); selective detection using single-chain sulfopeptide-specific phage antibodies (e.g. p.14, line 30 – p.17, line 11) and sulfopeptide-specific monoclonal antibodies (e.g. p.17, lines 13-29); and specific detection of chemically labeled O-serine and threonine sulfonation (e.g. p.8, line 15 – p.9, line 2; see also exemplification at p.19, lines 12-26). The specification amply describes and exemplifies the claimed methods.

The Specification teaches and exemplifies application of the methods to diverse O-serine and threonine sulfonated proteins and peptides of diverse cell types and across diverse life forms using a variety of established specific detection methodologies. As noted by the Action, one of these detection methods requires generating specific antibody reagents; however, techniques for doing so are amply described and exemplified (e.g. p.14, line 30 – p.17, line 11; p.17, lines 13-29), and squarely within the bounds of permissible experimentation as a matter of established law (e.g. *In re Wands*, 8 USPQ2d 1400, Fed Cir 1988).

Though there is no prima facie case of non-enablement, for good measure applicants provide herewith affirmative evidence in the form of an expert Declaration averring to the foregoing, and confirming that the Specification does indeed enable one skilled in the art to practice the invention as claimed without undue experimentation.

The Examiner is invited to call the undersigned with any suggestions for amending the claims or further clarifying any of the foregoing. Please charge any necessary fees or time extensions relating to this communication to our Dep. Acct. No.19-0750 (order UCSF04-016).

Respectfully submitted,
Science & Technology Law Group



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Encl. Declaration under 37CFR1.132.

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